IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

BAYER HEALTHCARE LLC,

Plaintiff,

Case No. 08-C-0953

vs.

NORBROOK LABORATORIES, LTD.,
and NORBROOK, INC. USA,

Defendants.

PLAINTIFF BAYER HEALTHCARE LLC'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION PURSUANT TO BAYER'S DISCOVERY REQUESTS OF APRIL 11, 2011

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Leaving aside the unhelpful rhetoric and inaccuracies, Norbrook's opposition demonstrates that the parties agree on the central enablement inquiry that the Court ultimately will have to resolve at trial: whether a person of ordinary skill could have prepared formulations of fluoroquinolones to be administered in a single high dose to treat bovine respiratory disease ("BRD") using the disclosure of the '506 patent. Opp. at 2. Many of the factual inquiries underlying that ultimate question are not disputed. For instance, it is not disputed that the specification of the '506 patent provides examples showing the administration of enrofloxacin to treat BRD in a single high dose. Kim Decl. Ex. 1[1], 2:22-3:37; Opp. at 2. Nor is it disputed that the '506 patent discloses that other formulations or compositions for use in the claimed treatment "can be prepared by art-known techniques" of combining the active ingredient with various carriers to obtain, typically, "an injectable solution." Kim Decl. Ex. 1, 1:61-2:10. And the patent provides examples of the carriers that may be used to prepare the formulations. Kim Decl. Ex. 1:61-2:10; Opp. at 2.

The salient question underlying the enablement dispute, therefore, is whether given this guidance, the level of skill and knowledge in the art of formulation was sufficient to enable the preparation and use of formulations that were not specifically exemplified in the '506 patent. Norbrook and Dr. Byrn contend that the answer is no. In particular, they assert that the difficulties that pharmaceutical companies generally face when trying to develop and test new formulations, principally created by differences in the "solubility," "absorption," and "intraconversion" of the active ingredients being formulated, render the required experimentation

[1] "Kim Decl." refers to the July 8, 2011 Declaration of Dillon Kim (dkt. 209) and exhibits (Exs. 1-8).

undue. Ex. A ¶¶ 35-36, 57[2]; Opp. at 6-8. In other words, Norbrook asserts that, where different active pharmaceutical ingredients are concerned, there are no general principles that can be applied to formulation of products. Under this view, a specific description of each of the formulations used in the practice of Bayer's claims would be necessary to enable the claims.

Bayer disagrees. Bayer asserts that the fact that active ingredients have different properties, with regard to solubility, stability, and absorption, is a basic principle that formulators understand, and it does not prevent those with skill in the art of formulation from readily preparing simple formulations such as those used in the patent. Br. at 5-6, *see* Ex. E (Palmieri Decl.) at 2-3. Formulators readily do so by modifying existing formulations of the same or different active ingredients, using well-known techniques and principles.

Of course, whether Norbrook or Bayer is correct as to the ultimate enablement issue will be decided at trial. What is not disputed, however, is that the issues of differing solubility, stability, and absorption (among others) identified by Norbrook and Dr. Byrn <u>are not unique to fluoroquinolones</u>. Rather, it is beyond cavil that those same issues, and the techniques used to address them, are <u>identical</u> for formulators irrespective of whether they are formulating a quinolone or non-quinolone active ingredient. Norbrook's rhetoric and inaccuracy-laden opposition does not—and cannot—obscure that central fact, which demonstrates the relevance, and indeed the necessity, of the discovery Bayer seeks here. Quite simply, given the undisputed fact that Norbrook's formulation of active ingredients other than fluoroquinolones is directed to addressing the same issues of solubility, stability, and absorption in the same manner that they would be addressed in the formulation of quinolone ingredients, it is simply untenable to permit

[2] The term "Ex." or "Exs." Refer to Exhibits to the Declaration of Jamie L. Simpson, submitted as part of Bayer's opening brief, dkt. 201, 202 (Exs. A-P), or to the Second Declaration of Jamie L. Simpson, submitted herewith (Exs. Q-X).

Norbrook simultaneously to assert that those issues are insurmountable without undue experimentation and yet shield from discovery its own efforts to address them.

Norbrook's attempt to obscure this dispositive fact by drawing a distinction between formulation of quinolones and non-quinolones that exists in neither scientific principle nor practice is wholly unpersuasive. The discovery sought by Bayer is central to the parties' core enablement dispute, and the Court should compel Norbrook to provide it.

ARGUMENT

A. Discovery Into the State of the Art Is Relevant

Based on principles of the microbiological and pharmacological action of fluoroquinolones in cattle, the inventors of the '506 patent were the first to propose that one high dose shot of a fluoroquinolone could be effective to treat bovine respiratory disease. Kim Decl. Ex. 1, 1:28-40. The inventors proved the concept to be correct in experiments with one particular quinolone called enrofloxacin. *Id.* 2:25-3:11. As Bayer will show at trial, the applicable microbiological and pharmacological principles at play dictate that the single high dose invention works with other fluoroquinolones as well.

The patent does not involve or claim to have invented novel formulations to be used in dosing animals. Indeed, no particular formulation was claimed, *id.* 4:14-15, because formulation is not the invention. The invention is treating cattle in a single high dose, instead of the state of the art multi-day dosing, using any simple, appropriate formulation. The formulation is not new. Bayer practices this single high dose treatment invention (and Norbrook proposes to practice it) using the exact same formulation that is used to treat cattle in the prior art, well-known multi-day regimen.

Nonetheless, Norbrook claims the patent is not enabled based on the lack of formulation information in the patent. Opp. at 6; Ex. A ¶¶ 30-54. However, the law is clear that "a patent

applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art." *Koito Mfg. Co. v. Turn-Key-Tech., LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). Nor does an applicant need to provide specific data or examples in a patent.[3] *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006); *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1308 (Fed. Cir. 2001) ("put[ting] to rest . . . argument that the patent is not enabled because the inventors failed to prepare" embodiments in patent).

The '506 patent directs the skilled artisan to look to "art known techniques" to prepare formulations. Kim Decl. Ex. 1, 1:60-64. The invention embodied in the patent was treating in a single high dose. The formulations were to be simple and obtained by reference to what was known in the art about formulating active ingredients. What was known in the art, whether tasks were routine or difficult, and the predictability of successfully preparing a formulation are thus highly relevant to enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (factors include "state of the prior art," "relative skill of those in the art," and "the predictability or unpredictability of the art.").

Norbrook disagrees, arguing that Bayer "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for missing information in the specification" and citing *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935 (Fed. Cir. 2010). Opp. at 14. But *ALZA*

[3] Hence, Norbrook's suggestions of malfeasance by Bayer for testing and providing data for "only one fluoroquinolone" are off base. Opp. at 5. It is irrelevant to enablement whether Bayer's inventors themselves conducted experiments on all of the fluoroquinolones in the '506 patent. The enablement inquiry turns on whether a skilled artisan could prepare the formulations as the patent indicates, not whether Bayer conducted the experiments itself. *Durel*, 256 F.3d at 1307-08; *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 374-76 (D.N.J. 2010). Similarly, the fact that extended release formulations had not been successful (Opp. at 5 n.3) is irrelevant, because the patent states that treatment works "without the need for special prolonged release formulations." Kim Decl. Ex. 1, 1:28-31. The invention involves avoiding those formulations, not making them.

stands for the straightforward proposition that the patent must disclose the point of novelty of the invention. 603 F.3d at 939 ("[W]hat one of the proper skill in the art knows cannot substitute for disclosure of novel aspects of the invention . . . ."); *Emergency Fuel, LLC v. Penzoil-Quaker State Co.*, 71 Fed. App'x. 826, 831-32 (Fed. Cir. 2003)). It does not suggest that the patent must disclose the aspects of the patent that are not novel. Indeed, the case law reflects exactly the opposite. *Koito*, 381 F.3d at 1156; *Falkner*, 448 F.3d at 1365 (specification should not include what is known in the art).

For instance, in *Eli Lilly*, the Court held that a method of use claim that did not require a novel formulation to practice it was enabled because a skilled artisan could make a formulation to practice the method, without undue experimentation. 731 F. Supp. 2d at 375-76. The Court looked outside of the four corners of the patent to what was known in the formulation art to conclude that the patent was enabled. The Court distinguished *ALZA*, explaining that "the allegedly non-enabled formulation [in *ALZA*] was part of the invention's novelty." *Id.* at 375.

In this case, as in *Eli Lilly*, the point of novelty is the particular method of use—that one could treat BRD effectively using a single, high dose. Kim Decl. Ex. 1, 4:10-29. The formulation is not the point of novelty. *See Eli Lilly*, 731 F. Supp. 2d at 375 ("Indeed, the ALZA Court appeared to recognize that methods for developing certain conventional dosage forms—forms that were not part of the invention's novelty—were well known."). As to non-novel aspects, such as the simple formulation used in the novel treatment of Bayer's patent, there is no requirement whatsoever of anything more than the standard and ubiquitous reference to techniques known in the art.

The discovery Bayer seeks will help establish this central point: that formulation techniques are well-known and could be applied readily to formulate active ingredients with different properties.

B. Non-Flouroquinolone Formulations Are Relevant

Norbrook asserts that there is no basis to inquire into its non-fluoroquinolone formulation work because its argument, as advanced in Dr. Byrn's report, is limited to fluoroquinolones. Opp. at 7 (Bryn "mentions no drugs other than fluoroquinolones"). That is wrong. The issue is not whether Dr. Bryn "mentioned" any non-fluoroquinolone drugs.[4] The real issue, which Norbrook cannot refute and seeks to avoid, is that principles that Norbrook and Dr. Byrn contend make formulations difficult to prepare are general principles that apply equally and identically to fluoroquinolones and non-fluoroquinolones alike. Ex. E (Palmieri Decl.) ¶¶ 6-7. They are the same principles—such as accounting for solubility in preparing a new formulation—that Norbrook applies in practice every day, whether the drug being formulated is a fluoroquinolone or some other active ingredient. *Id.* ¶ 8. Skilled formulators addressing these same issues with respect to formulation preparation routinely gather pertinent (previously unknown) information in advance of formulating drug products, *but see* Ex. A (Byrn Rpt.) ¶ 35; they draw on their years of formulation training to determine which formulation recipe works for the particular drug, *but see id.*; and they perform this work expending a routine amount of time and effort, *but see id.* at ¶ 43; Ex. E ¶¶ 6-7.

Nonetheless, a premise of Dr. Byrn's report is that a formulator would need more "compound-specific information" than is provided in the '506 patent on parameters such as "solubility" and "absorption" in order to construct an "acceptable composition" for a

[4] Dr. Bryn's report contained both statements that were specific to fluoroquinolones, *e.g.*, Ex. A ¶ 38, as well as statements that were not, *e.g.*, *id.* ¶ 57. *See also* Br. at 11.

fluoroquinolone. Ex. A ¶ 35. Norbrook does not suggest that there is something about fluoroquinolones that makes gathering this type of information about them or researching their characteristics more difficult than for non-fluoroquinolones; rather, Norbrook simply points to the absence of this information in the patent. Opp. at 7. Bayer believes that any information on fluoroquinolones that is not recited in the '506 patent can be gathered from the literature or determined by routine studies, as it is with any other drug, and that is not the roadblock to development that Dr. Bryn and Norbrook suggest.

A further premise of Dr. Bryn's report is that the absence of "working examples" with fluoroquinolones other than enrofloxacin makes creating an "acceptable composition" with other fluoroquinolones difficult. Ex. A ¶ 14; Opp. at 6. Dr. Palmieri disagrees and believes that it is the routine work of a formulator to modify one formulation of a fluoroquinolone, like enrofloxacin, to create another formulation. Ex. E ¶ 6. This dispute is critical to the enablement inquiry, and the discovery Bayer seeks is highly relevant to resolving it. *Eli Lilly*, 731 F. Supp. 2d at 374-76 (claim, like Bayer's, enabled because "development of [] formulations" was "common in the art and taught by standard textbooks used by pharmacy students").

Norbrook does not deny that the Norbrook formulations that are the subject of this motion did not exist before Norbrook formulated them. Opp. at 10-11; Cromie Decl. ¶ 7. Nor does Norbrook suggest that formulating products was difficult or beyond the level of one of ordinary skill in the art. *Id.* Rather, Norbrook argues that there is "no analogue" in its experience with these twelve drugs to the formulation of fluoroquinolones in the '506 patent "because few of the fluoroquinolones referenced in the patents-in-suit in this case were commercially available around the 1995 timeframe." Cromie Decl. ¶ 8; Opp. 11 n.7. But this crucial assumption on which Norbrook's argument rests is, at best, misleading. Whether or not

they were commercially available, numerous injectable fluoroquinolone formulations were known and had been described in the literature by the time Bayer filed its patent, including formulations of norfloxacin, ciprofloxacin, sparfloxacin, and enrofloxacin. *E.g.*, Ex. T at 672 (norfloxacin formulation), Ex. U at 2669 (ciprofloxacin and sparfloxacin formulations); Ex. V at 126-27 (enrofloxacin formulation).[5]

Norbrook contends that its research is distinct from that required to practice the '506 patent because Norbrook had an existing formulation containing the same active ingredients in hand when it sought to prepare its (different) formulations. But the same is often true for the person of ordinary skill practicing the '506 patent, who would have possessed knowledge of formulations such as those cited above and—like Norbrook has done with its twelve products—applied techniques known in the field to prepare another formulation. The question is, for the formulations the skilled artisan wants to prepare, whether the various properties of the active ingredient—its solubility, absorption, etc.—are roadblocks that cannot be overcome without undue experimentation (as Dr. Bryn says) or simpler issues addressed by formulators every day with relative ease (as Dr. Palmieri asserts). The ease or difficultly of preparing formulations by making such modifications is the subject of both the enablement dispute and the discovery Bayer seeks.

Norbrook asserts that Bayer has not demonstrated that the twelve products have "anything in common with fluoroquinolones." Opp. at 10, 16 ("unfathomable that Bayer could expect to find anything . . . remotely probative of the enablement issue"). That criticism misses the mark. The question is not whether the compounds Norbrook formulated have anything in

[5] To the extent Norbrook suggests that FDA-approved formulations were required for the formulation to be of any use, that would not be the starting point of the scientific inquiry. *Eli Lilly*, 731 F. Supp. 2d at 376 (enablement inquiry is "scientific inquiry" and not "regulatory inquiry").

common with fluoroquinolones but, rather, whether the formulation of those compounds has anything in common with the formulation of fluoroquinolones. In that relevant respect, they have everything in common and have every "bearing on the degree of experimentation that would be required to enable the '506 patent," for the reasons that Bayer and Dr. Palmieri explain: the process for formulating these twelve injectable drugs is the same as the process for formulating injectable fluoroquinolones. *Supra* at 6; Ex. E ¶ 7.[6]

Norbrook argues that "drug formulation 'in general' is not the enablement issue." Opp. at 11 n.8. That is wrong. Drug formulation is at issue because Norbrook put it at issue. Had Norbrook wished to avoid this issue, *see* Opp. at 11-12, as it now hopes to do in discovery but not at trial, Norbrook could have identified particular principles or properties of fluoroquinolones that made them especially difficult to formulate into the simple injectable formulations used to practice Bayer's patented method. But no matter how much Norbrook parses or tries to rewrite the Bryn Report, Opp. at 6-8, the simple truth here is that Norbrook did not advance that enablement argument. Instead, Norbrook relied on general principles and assertions about the difficulty of preparing formulations in view of differing solubility, absorption, and stability. Br. at 4-6. The consequences of Norbrook's decision is that discovery directed at undercutting those arguments is highly relevant to this case. *Compagnie Noga D'Importation et D'Exportation S.A. v. Russian Fed'n*, 2008 WL 3833257, at *6 (S.D.N.Y. Aug. 15, 2008) ("[Plaintiff's] own documents undermine its expert's interpretation and support Defendant's expert's interpretation.") (Ex. Q); *Cooley v. Lincoln Elec. Co.*, 2011 WL 841535, at *17 (N.D. Ohio Mar.

[6] Norbrook baselessly criticizes Bayer's expert Dr. Palmieri for a declaration he submitted in another case. Opp. at 11 n.8. Norbrook's attack is off-base. There are, of course, certain specific, sophisticated, and atypical formulations that can be challenging to prepare, potentially including the formulation at issue in that case. Those atypical formulations are not at issue here, where the patent instructs a skilled artisan to prepare basic formulations using "art-known techniques."

7, 2011) (Ex. R); *Bitler Inv. Venture II, LLC v. Marathon Ashland Petrol. LLC*, 2007 WL 465444, at *7 (N.D. Ind., Feb. 7, 2007) (Ex. S).

C. Injectables Are the Proper Focus

Bayer has focused its discovery requests on injectable formulation because the patent teaches that the "typical[]" dosage form with which to practice the invention is an "injectable solution." Kim Decl. Ex. 1, 2:5-6; *Eli Lilly*, 731 F. Supp. 2d at 373. Norbrook suggests that Bayer's "position on injectables is untenable" because the claim is not limited to injectables. Opp. at 10. But the enablement inquiry depends on how a skilled artisan would practice this claim in view of the specification's teaching, and the specification here cites states that "typically" one should use injectables. Kim Decl. Ex. 1, 2:5-6; *Eli Lilly*, 731 F. Supp. 2d at 373. That is what one of skill in the art would prepare in the first instance, and the dispute, as it relates to this motion, is whether that is easy or hard.

If, however, Norbrook is concerned that Bayer has limited its discovery requests to injectables, Norbrook could remove that limitation and produce its non-injectable formulation research as well. Bayer imposed that limitation in an effort to address Norbrook's concerns about burden. The notion that Norbrook at once complains that the discovery sought is too burdensome, Opp. at 9-12, and that it is unduly limited to injectables, Opp. at 9-10, reveals the shell game necessary to obscure the determinative fact: that the narrow discovery at issue strikes at the heart of Norbrook's enablement defense.

D. Norbrook Is Not the Only Target of Discovery

Norbrook suggests that Bayer is trying to "punish Norbrook" for raising its enablement defense and that Bayer has not otherwise developed its case as promised. Opp. at 1,17. But that could not be farther from the truth. Bayer has subpoenaed numerous companies with potentially relevant information (including Pfizer, identified in Norbrook's opposition at 12 n.9, from whom

Bayer has been seeking discovery informally). Ex. W. While Norbrook downplays the role of some of the companies that Bayer has subpoenaed, these entities, which engage in pharmaceutical "compounding," are in fact conducting formulation research. Compounding is no more than preparing formulations to meet specific patient needs and is directly relevant to the enablement inquiry, as *Eli Lilly* explained. 731 F. Supp. 2d at 376.[7]

E. Any Alleged Burden to Norbrook Does Not Excuse Discovery

Norbrook's reliance on burden to avoid the discovery that Bayer seeks essentially would have the court excuse parties from undertaking the normal discovery in federal civil litigation simply by submitting an affidavit attesting to the regular process of document collection, review and production. *See* Opp. at 16-17. But the law is clear: "[t]he mere fact that producing documents would be burdensome and expensive and would interfere with party's normal operations is not inherently a reason to refuse an otherwise legitimate discovery request." *Baine v. GMC*, 141 F.R.D. 328, 331 (M.D. Ala. 1991); *accord Biliske v. American Live Stock Ins. Co.*, 73 F.R.D. 124 (W.D. Okla. 1977); *Keco Indus., Inc. v. Stearns Elec. Corp.*, 285 F. Supp. 912 (E.D. Wis. 1968); *Speedrack, Inc. v. Baybarz*, 45 F.R.D. 254 (E.D. Cal. 1968); *Technograph, Inc. v. Tex. Instruments, Inc.*, 43 F.R.D. 416 (S.D.N.Y. 1967); *Rockaway Pix Theatre, Inc. v. Metro-Goldwyn-Mayer, Inc.*, 36 F.R.D. 15 (E.D.N.Y. 1964). Norbrook is a sizeable multi-national company and, if it prevails in this case that it initiated by filing its generic application, is

[7] Norbrook also accuses Bayer of not producing its own non-fluoroquinolone related documents. Opp. at 17 ("Bayer has not produced any of the same types of documents to Norbrook regarding its own work on non-fluoroquinolone formulations."). But Norbrook has never asked for those documents. And Bayer has agreed to produce virtually everything that Norbrook requested, which amounts to documentation regarding more formulations than Bayer has sought from Norbrook. Whatever additional relevance Bayer's non-fluoroquinolone documents may have, they cannot substitute for Norbrook's own documents demonstrating the ease of formulating which undermine its expert report. *Compagnie*, 2008 WL 3833257, at *6 ("[Plaintiff's] own documents undermine its expert's interpretation and support Defendant's expert's interpretation."); *Cooley*, 2011 WL 841535, at *17; *Bitler*, 2007 WL 465444, at *7.

in a position to capture a $50 million annual market; Bayer's discovery requests are proportional to the importance of the case and the sophistication of the parties. *See Keco*, 285 F. Supp. at 914 ("[P]laintiff is seeking damages for . . . over half a million dollars. Thus, it is not in a strong position to complain of burdensome requests.").

Indeed, notwithstanding that Bayer had disputed the relevance of Norbrook's discovery requests into fluoroquinolone dosage formulation beyond injectables—believing that the work done to formulate feeds and ear drops have nothing to do with whether Bayer's patent is enabled—Bayer has agreed to produce these formulations documents to the extent it can locate them. The discovery sought from Norbrook is no more burdensome than that discovery Norbrook demanded from Bayer. For example, many of the Bayer files are likewise old, paper files. *See* Monachello Decl. ¶¶ 4, 6-7 (Ex. X). These documents are stored in archived boxes located in "caves" that are not well indexed and cover formulation work done over 20 years ago. *See id.* ¶¶ 5-7. The manhours and dollars expended by Bayer to provide this discovery is no less, and perhaps much more, than what Norbrook must expend. *See id.* ¶ 8. And to date, the discovery in this case has weighed much more heavily on Bayer than Norbrook. Bayer has produced over 15,000 documents totaling more than 165,000 pages, while Norbrook has produced just 3,800 documents and 20,000 pages, despite asserting both invalidity and non-infringement. Simpson Decl. ¶ 3.

Norbrook raised the enablement defense late in the case, and Bayer is seeking, by this motion, the discovery it would have taken had this defense been raised earlier. Norbrook's argument and associated declaration are simply reflective of the burdens litigants regularly face in discovery. Litigants routinely pour through boxes "some of which are not warehoused or catalogued in any easy, organized manner," Cromie Decl. ¶ 12; *see Baine*, 141 F.R.D. at 331

("Nor can the lack of an adequate filing system insulate a party from discovery."). Furthermore, in many litigations, the discovery sought involves decades-old information (as with the documents Bayer is producing), so the fact that Norbrook has documents from "10-15 years" ago and "20-25 years" ago is not irregular. Cromie Decl. ¶¶ 13-16; *see Baine*, 141 F.R.D. at 332 (documents over ten years old).

Furthermore, Norbrook vastly overstates what Bayer is requesting. While Dr. Cromie's affidavit suggests that Bayer is seeking "manufacturing and operational related" documents and "QC/Change Control" related documents for each of these 12 formulations, Cromie Decl. ¶ 17, Bayer has never sought these downstream-type documents. Bayer has requested documents reflecting formulation development work, *i.e.*, documents reflecting facts that go to the ease or difficulty of developing the formulation. Ex. D, Request Nos. 56 and 66; *see also* Bayer's Proposed Order (dkt. 201-1).[8]

Finally, in contrast to Norbrook's demands on Bayer, Bayer has consistently indicated its willingness to accept summary documents (such as reports instead of individual laboratory records), or "documents sufficient to show" in response to Norbrook's concerns about burden.[9] Ex. I. This would substantially lessen the purported burden of "copying all hard copy documents." Cromie Decl. ¶ 17 Ordering Norbrook to produce summary documents or

[8] Indeed, it appears from Dr. Cromie's preliminary efforts to consider the scope of Bayer's discovery request for purposes of responding to Bayer's motion that Norbrook may not be in possession of formulation documentation for two products (Norocillin and Pen G Procaine Aqueous Sterile Benzathine). Cromie Decl., ¶¶ 14-15. Assuming this is true, Norbrook would have no documents to search for and produce, alleviating any burden as to these products. Dr. Cromie's declaration is the first time that Bayer has been made aware that Norbrook may not otherwise have documentation for the formulation of these products, despite sending Norbrook a letter with a particularized request for these twelve drugs before filing the instant motion. *See* Ex. I; Cromie Decl. ¶¶ 14-15.

[9] Norbrook declined further meet and confer regarding the logistics of any discovery outside of fluoroquinolone drugs, based on Norbrook's overly restrictive view of relevance.

documents sufficient to show the facts reflecting the ease or difficult of formulation can minimize this burden on Norbrook.[10]

CONCLUSION

For the forgoing reasons, Bayer respectfully requests that this Court grant Bayer's motion to compel on Bayer's discovery requests served on April 11, 2011.

[10] The *Moore* case, cited by Norbrook, Opp. at 17 (citing *Moore U.S.A. Inc. v. Standard Register Co.*, 206 F.R.D. 72 (W.D.N.Y. 2001), denied further discovery where the party had already provided exemplary reports. *Moore*, 206 F.R.D. at 74. Here, Norbrook is resisting production of any exemplary reports or other documents reflecting its formulation work.

Date: July 22, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2011, a true and correct copy of the foregoing was caused to be served to all counsel of record by electronic mail (ECF).

/s/ Stanley E. Fisher